(8)

No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONERS

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This supplemental brief is filed pursuant to Rule 15.8 of the Rules of this Court, to address arguments made by the United States in its brief as amicus curiae ("U.S. Br."). The United States agrees that the Court of Appeals' decision below applies the wrong standard and conflicts with the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006), and that the question of law at issue is important and should be settled by this Court, thereby satisfying the criteria of Rule 10(a) and (c). Nonetheless, the United States recommends that the Court deny certiorari — thereby allowing pervasive uncertainties affecting the $200 billion prescription drug industry to persist — until some unidentified, more "attractive vehicle," arising in the post-2003 regulatory context, wends its way to the Court.

As shown in the Argument below, the United States' analysis overlooks multiple points that show this case is, in fact, a compelling one for certiorari. In summary:

A. Federal law issues are not "moot" here, for three reasons:

1. An injunction can properly enjoin a repeated antitrust wrongdoer from engaging in similar unlawful practices, so that as a matter of law, Petitioners' injunctive claim under federal law is not "moot." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 133 (1969);

2. The effect of a federal patent on a state law antitrust claim for damages raises a question of federal defense, as to which certiorari is just as appropriate as with regard to a federal affirmative claim. *Cf. Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 12 n.12 (1983) (concerning federal preemption defense); and

3. The same conduct is unlawful under both state and federal antitrust law. Thus, this case falls squarely within the rule that it is appropriate for this Court to review interpretations of state law that have been "influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng'g, P.C.*, 467 U.S. 138, 152 (1984).

B. Any unique aspects of this case do not affect the answer to the question presented; instead, the same broad questions of law are presented in this case as in other cases.

C. This case presents a straightforward opportunity to resolve important legal issues surrounding reverse payment agreements that will likely be more complex to resolve in connection with later agreements, which increasingly rely upon complicating mechanisms to obscure payments to the generic firm in return for delay, and thus will involve *more* "unique facts" than this case does.

ARGUMENT

A. 1. The United States notes that Petitioners sought injunctive and declaratory relief under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and contends that claim became moot upon the expiration of Zeneca's patent in 2002. U.S. Br. 17. One of the objectives when these actions were filed was, indeed, to enjoin Respondents' compliance with the challenged Agreements and to facilitate commercial launches of generic tamoxifen.[1] While this is now unnecessary, broader relief to prohibit Respondents (particularly Respondent Barr Laboratories) from engaging in pay-for-delay settlements may nonetheless be appropriate. As noted in the petition, Barr has been paid to delay efforts to market generic Cipro®, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), and generic Ovcon 35®, *see Federal Trade Commission v. Warner Chilcott Holdings, Inc.*, No. 1:05-cv-021790CKK (D.D.C.), as well as numerous other leading drugs.[2]

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1. The first constituent action in this multidistrict litigation to seek federal injunctive relief is the *Joblove* action (E.D.N.Y. No. 1:00-cv-6046), filed on October 6, 2000. *See* Pet. 5.

2. *See* C. Scott Hemphill, *Drug Patent Settlements Between Rivals: A Survey*, at 3 (Mar. 12, 2007) attached to Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Hearing on H.R. 1902, May 2, 2007, *available at*: http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg. 050207.Hemphill-testimony.pdf. ("Of the seventeen innovators and eighteen generic firms that are party to the

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Pet. 7-8, n. 8. Petitioners' complaint sought "such other relief as [the district court] may deem just and proper under the circumstances," C.A. App. A-58, and Petitioners (including large third-party payors who pay for most prescription drugs) have a broad interest in ensuring that cost-saving, generic pharmaceuticals are available without collusively-imposed delays.

In *Zenith*, the Court stated that "[w]e see no reason that the federal courts, in exercising the traditional equitable powers extended to them by § 16 [of the Clayton Act, 15 U.S.C. § 26], should not respond to the salutary principle that when one has been found to have committed acts in violation of a law he may be restrained from committing *other related* unlawful acts." 395 U.S. at 133 (citation omitted; emphasis added). And even before *Zenith*, courts recognized that the voluntary cessation of illegal conduct does not render claims for injunctive relief moot. *U.S. v. W. T. Grant Co.*, 345 U.S. 629, 632-33 (1953). In *W. T. Grant*, the government brought civil actions challenging interlocking corporate directorates. A director resigned from some of the posts to eliminate the interlocks, but the Court held that these steps did not moot the claim for injunctive relief.

> Both sides agree to the abstract proposition that voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, i.e., does not make the case moot. A controversy may remain to be settled in such circumstances, e.g., *a dispute over the legality of the challenged practices*. The defendant is free to return to his old ways. *This, together with a public interest in having the legality of the practices settled, militates against a mootness conclusion....*
>
> The case may nevertheless be moot if the defendant can demonstrate that there is *no*

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settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlements with respect to eight different drugs.")

> *reasonable expectation* that the wrong will be repeated. The burden is a heavy one.

W. T. Grant, 345 U.S. at 632-33 (emphasis added, citations and footnotes omitted); *accord*, *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000) ("It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.") (internal quotation marks and citations omitted).

The Court's rationale applies with even greater force where, as here, the challenged practice has been expressly deemed *lawful* by the lower courts. In these circumstances, the reasonable expectation is that repetition is not only possible, *but inevitable*. *See* Reply Brief 3-4, 1a (noting recent spike in reverse payment settlements). While courts cannot enjoin "all future violations of the antitrust laws," they can and should enjoin continuing unlawful practices, such as pay-for-delay settlements, that squelch generic competition. *Zenith*, 395 U.S. at 133 ("[W]hen the purpose to restrain trade appears from a clear violation of the law, it is not necessary that all of the untraveled roads to the end be left open and that only the worn one be closed.") (citation and quotation marks omitted).

In any event, the question presented relates to whether Petitioners alleged a violation of the Sherman Act in the first place, and not the scope of a potential injunction. The United States agrees that the lower courts were wrong in holding that Petitioners failed to allege such a violation. Petitioners do not contend that it is impossible for a challenge to such an agreement to reach this Court before the expiration of the pertinent patent, nor is such "evasion of review" necessary in order for a broad injunction to be available under *Zenith*. *Cf.* U.S. Br. 17. Instead, the limited life span of patents, the ubiquity of pay-for-delay agreements and their impact on the national economy, the conflicting circuit court standards, and the strong public interest

in antitrust enforcement, all militate strongly in favor of granting certiorari in this case.

2. In addition, the tamoxifen patent has been raised as a federal defense that immunizes conduct that would otherwise violate antitrust laws — federal or state. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003) ("The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim. . . ."); *In re Stock Exchanges Options Trading Antitrust Litig.*, 317 F.3d 134, 151 (2d Cir. 2005) ("Most immunities are affirmative defenses."). The same federal interests advanced by a grant of certiorari to address federal law claims are equally advanced by certiorari to address a federal law defense to a state law claim. Thus, even when a state court rejects a claim of federal preemption, such a decision is reviewable by the Court notwithstanding that the assertedly preempted claim is a state law claim *Franchise Tax Board*, 463 U.S. at 12 n. 12 (citing *Fidelity Federal Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141 (1982)).

3. Even absent the injunctive claim and the federal patent defense, the legality of reverse payment settlements is squarely raised by Petitioners' claims for damages under state antitrust statutes. The United States notes that "petitioners have not identified even a single state statute (of the many on which the complaint relied) that has been construed as being coterminous in all respects with federal antitrust law." *Id.* at 18. However, the United States conflates differences between state and federal law concerning who may bring suit (i.e., standing) with the *uniformity* of state and federal law concerning *conduct* that constitutes an antitrust violation. Differences between federal and state antitrust statutes generally relate only to jurisdiction (state violations need not impact interstate commerce) and injured parties who may assert claims for damages.[3] On the other

3. While indirect purchasers lack standing to bring suit for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, *see Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), this Court has expressly left it to

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hand, it is well recognized that *conduct* that violates Sections 1 and 2 of the Sherman Act also will violate corresponding state statutes.[4] In fact, many state antitrust statutes expressly adopt federal antitrust precedents as controlling guidance. *E.g.*, Ariz. Rev. Stat. § 44-1412; D.C. Code Ann. § 28-4515; Iowa Code § 553.2; N.M. Stat. Ann. § 57-1-15; S.D. Codified Laws § 37-1-22; W. Va. Code Ann. § 47-18-16.

It is not surprising, therefore, that the Court of Appeals' analysis focused exclusively on violation of the Sherman Act. The Court of Appeals rightly perceived that question to be dispositive, which belies the United States' far-fetched argument that "the relevance of that determination [of federal law] to the state laws at issue is entirely uncertain." U.S. Br. 18. As "the adequacy and independence of any possible state law ground is not clear from the face of the opinion," this Court should "accept as the most reasonable explanation" that the Court of Appeals "decided the case the way it did because it believed that federal law required it to do so." *Michigan v. Long*, 463 U.S. 1032, 1040-41 (1983). At a minimum, the Court of Appeals' "interpretation of state law has been influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes*, 467 U.S. at 152. It is clearly appropriate for this Court to grant certiorari to correct such misapprehensions as to what conduct is unlawful under the Sherman Act.

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the states to determine if state laws should permit indirect purchasers to bring antitrust damage suits. *See California v. ARC America Corp.*, 490 U.S. 93, 102-03 (1989).

4. *See, e.g., Grams v. Boss*, 294 N.W.2d 473, 480 (Wis. 1980) ("We have repeatedly stated that [Wis. Stat.] sec. 133.01, Stats., was intended as a reenactment of the first two sections of the federal Sherman Antitrust Act of 1890 ... and that the question of what acts constitute a combination or conspiracy in restraint of trade is controlled by federal court decisions under the Sherman Act."); *see also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 900 (6th Cir. 2003); *U.S. v. Microsoft Corp.*, 87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000), *affirmed in part rev'd in part on other grounds by*, 253 F.2d 34 (D.C. Cir. 2001).

B. The United States may be correct that the precise factual circumstances of this case are unlikely to recur, but any unique facts do not detract from the question squarely raised in the petition — *i.e.*, under what general circumstances are reverse payment settlements to exclude generic competition unlawful? There is certainly no suggestion that application of the erroneous standard adopted by the Court of Appeals is limited by the unique facts of this case. *Cf.* U.S. Br. 16 n. 7 (suggesting that *Cardizem* does not extend beyond the purportedly unique circumstances there); *see also* Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006) at 7-8.[5] The Court of Appeals recognized that, notwithstanding unique facts, "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a. The primary "uniqueness" that the United States identifies in this case involves a change in the law governing vacatur of judgments. U.S. Br. 19. As the United States recognizes, however, that fact is germane only to a more general assessment of the strength of the patent. *Id.* Such an assessment of patent strength could involve anything in the entire realm of patent law, and thus will involve "unique facts" in every case. To wait for some hypothetical, unidentified future case having no "unique facts" would simply leave important legal issues unresolved indefinitely.

Indeed, by contending that because the challenged agreements occurred after a judgment of patent invalidity, a decision emphasizing that factor "might shed little light on the proper disposition of future cases challenging reverse-payment settlements in other factual settings," U.S. Br. 19, the United States seems to suggest that certiorari should be denied because Petitioners' case — which they *lost* below — is *too strong* on the merits to produce a generally applicable precedent. This Court is able to craft its opinions to avoid undue emphasis on one case's particular facts. Speculation to the contrary should

5. *Available at:* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

not trump the strong public interest in ensuring proper antitrust enforcement, especially in an unusually *strong* case. *See Zenith Radio*, 395 U.S. at 130-31.

C. Finally, the United States suggests that it may be preferable to await a case that arises under the post-2003 regulatory regime, further noting that Congress is considering legislation that would prohibit reverse payments in settlements with ANDA filers. U.S. Br. 19-20 & n.9 (citing S. 316, 110th Cong., 1st Sess. § 3 (2007); H.R. 1902, 110th Cong., 1st Sess. § 2 (2007)).[6] This suggestion is very odd, given that in its brief in the *Schering* case, the other cases identified as a basis for assuming that a conflict could "develop" were all pre-2003 cases. Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 19 ("Schering Br.").

The United States' brief unreasonably exaggerates the significance of the 2003 amendments. The Second Circuit separately rejected the aspect of Petitioners' allegations that rested on alleged conspiracy with Barr to manipulate the 180-day exclusivity period, on four separate legal grounds. Pet. App. 59a-64a. Petitioners have not included any of those four legal issues in their question presented. Instead, the only legal issue that Petitioners have sought to raise with this Court is a broad question, concerning lawfulness of settlement agreements

6. Even if the legislative process ultimately prohibits reverse payment settlements with ANDA filers, U.S. Br. 20 n.9 — at best, a highly uncertain proposition — there will be no remedy for the breast cancer patients and prescription benefit providers who were harmed by paying supra-competitive prices for tamoxifen. The proposed legislation applies only to pharmaceuticals, and the Court of Appeals' opinion may inspire similar anticompetitive agreements in other industries. Moreover, even in the pharmaceutical context, the proposed legislation has been criticized by defense attorneys as an "indiscriminate legislative solution to a delicate problem." N. Stoll and S. Goldfein, *Reverse Payments: A Question for Court or Congress*?, New York Law Journal (April 17, 2007). "Individual examination of reverse payment agreements by courts, under a proper standard articulated by the Supreme Court, is the best way to make sure procompetitive brand-generic settlements are promoted and anticompetitive horizontal allocations are prevented." *Id.*

themselves, as to which pre-2003 and post-2003 cases do not differ. This case presents a straightforward opportunity to address that important question now. *See* Pet. 9-10.

It is highly unlikely that post-2003 agreements — if they are subjected to antitrust enforcement at all — will present the issues with greater clarity. As recently explained in testimony before Congress, reverse payment settlements have occurred in two distinct waves.[7] The first wave began in 1993 and ended in 2000, after the Federal Trade Commission made clear its opposition to pay-for-delay settlements. The second wave began in 2005, in "direct response to the failure of federal courts [in *Schering-Plough* and *Tamoxifen*] to recognize and resolve the pay-for-delay issue." Hemphill Testimony at 8. "That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay." *Id.*

> In the earliest settlements, such as tamoxifen, BuSpar, Zantac and Cipro settlements, payment *was a relatively straightforward affair*. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. Modern settlements also entail payment for delay, *but the parties avoid a straight conveyance of cash*, preferring instead to employ a variety of alternative forms of payment.

Id. at 8-9 (emphasis added). In sum, in light of uncertainties created by divergent legal standards in the different Circuits, brand-name firms increasingly rely upon complicating side deals as "means to smuggle compensation to the generic firm." *Id.* at 9. Such side deals in the post-2003 regulatory environment are likely to present significantly *more* "unique facts" than this case does. *Cf.*, Schering Br. at 12-13 (recommending denial of certiorari because, *inter alia*,

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7. Testimony of C. Scott Hemphill, Associate Professor, Columbia Law School, House Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007 (May 2, 2007) ("Hemphill Testimony") at 7; *available at:* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf.

"[t]he court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's product.") (citation to record omitted).

Opportunities for this Court to address comparatively straightforward, "first wave" agreements are dwindling.[8] To await some other, unidentified "vehicle" that hypothetically might be more "attractive" for review is a recipe for the indefinite postponement of important issues, which the United States concedes already have generated a split between the Circuits, and which create serious legal planning uncertainties for pharmaceutical companies on a regular basis. Moreover, while this Court awaits a hypothetically "more attractive" vehicle, drug purchasers, including the United States and Petitioners, would continue to pay countless billions in overpayments, as the "second wave" of pay-for-delay deals triggered by the erroneous decision of the Second Circuit below continues unabated. In view of the United States' recognition that the decision below applied an incorrect legal standard, that the legal standard applied is too lax, and that the legal question raised is important and should be settled by this Court, certiorari should be granted. *See* Pet. App. 125a (Pooler, J., dissenting) ("A more searching inquiry and a less stringent standard are required to properly protect all interests.").

CONCLUSION

For the foregoing reasons and those stated in our petition and reply, the petition for a writ of certiorari should be granted.

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8. We are not aware of any pending antitrust litigation concerning Zantac or Buspar. Antitrust litigation concerning Cipro, which resulted in summary judgment in favor of defendants (*Ciprofloxacin*, 363 F. Supp. 2d 514), is currently on appeal in the same court that produced the divided opinion below. *See* 2d Cir. nos. 05-2851, 05-2852 & 05-2863. Merits briefing for *Ciprofloxacin* has been suspended pending resolution of a motion to transfer the cases to the federal circuit. Here, the Court of Appeals relied heavily on the *Ciprofloxacin* decision in upholding dismissal. *See* Pet. 11.

Respectfully submitted,

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